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AADA No.	Drug	Applicant
60–481	Tetracyline Oral Suspension, USP	Do.
60–515	Kanamycin Sulfate Injection	Apothecon, A Bristol-Myers Squibb Co., P.O. Box 4500, Princeton, NJ 08543–4500.
60–516	Kanamycin Sulfate Capsules, 500 mg	Do.
60–556	Neomycin Sulfate, USP (Nonsterile Bulk)	Penick Corp.
60–558	Erythromycin Estolate Oral Suspension, USP, 100 mg base/mL	Lilly Research Laboratories.
60–812	Chloramphenicol Hemisuccinate (Bulk)	Marion Merrell Dow, Inc.
60–828	Tetracycline Hydrochloride, USP (Bulk)	Valso Ltd.
60–829	Tetracycline, USP (Bulk)	Do.
61–137	Penicillin V (Bulk)	Lilly Research Laboratories.
61–525	Erythromycin Delayed-Release Tablets, 250 mg	Richmar International, Inc., 1706 Birch Rd., McLean, VA 22101.
61–586	Neomycin Sulfate Tablets, 500 mg	Eon Labs Manufacturing, Inc., 227–15 Conduit Ave., Laurelton, NY 11413.
61–967	Chloramphenicol Palmitate (Bulk)	Merrell Dow Pharmaceuticals, Inc., 2110 East Galbraith Rd., Cincinnati, OH 45215.
62–177	Erythromycin Ethylsuccinate Oral Suspension, 200 mg/5 milliliters (mL) and 400 mg/5 mL.	Lilly Research Laboratories.
62–261	Cephalexin Monohydrate (Bulk)	Do.
62–264	Gentamicin Sulfate Injection, USP	Wyeth-Ayerst Laboratories.
62–381	Neomycin and Polymyxin B Sulfates, Bacitracin Zinc, and Hydrocortisone Topical Ointment.	Pharmafair, Inc., 110 Kennedy Dr., Hauppauge, NY 11788.
62–386	Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment, USP.	Do.
62–389	Neomycin and Polymyxin B Sulfates, Bacitracin Zinc, and Hydrocortisone Ophthalmic Ointment, USP.	Do.
62–411	Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment, USP.	Do.
62–428	Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Suspension, USP.	Do.
62–443	Gentamicin Sulfate Ophthalmic Ointment, USP, 3 mg base/gram (g).	Do.
62–481	Erythromycin Ophthalmic Ointment, USP, 5 mg/g	Do.
62–485	Erythromycin Topical Solution, USP, 1.5%	Do.
62–547	Cephalothin Sodium and 5% Dextrose Injection, USP	Abbott Laboratories, Inc., Hospital Products Division Abbott Park, IL 60064.
62–548	Cephalothin Sodium and 0.9% Sodium Chloride Injection, USP	Do.
62–603	Nystatin and Triamcinolone Acetonide Ointment, USP	Pharmaderm, A Division of Altana Inc., 60 Bayliss Rd., Melville, NY 11747.
62–617	Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension.	Pharmafair, Inc.
62–623	Neomycin and Polymyxin B Sulfates and Hydrocortisone Ophthalmic Suspension, USP.	Do.
62–848	Cefadroxil, USP (Bulk)	Valso Ltd.
62–894	Sterile Cefazolin Sodium, USP 250 mg, 500 mg, 1 g, 5 g, and 10 g per vial.	Ben Venue Laboratories, Inc., 270 Northfield Rd., P.O. Box 46568, Bedford, OH 44146–0568.
62–908	Clindamycin Phosphate Injection, USP, 150 mg/mL	The DuPont Merck Pharmaceutical Co., 1000 Stewart Ave., Garden City, NY 11530.
70–292	Carbachol Intraocular Solution, USP, 0.01%	Pharmafair, Inc.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the AADA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective April 11, 1994.

Dated: February 23, 1994.

Murray M. Lumpkin,

Acting Director, Center for Drug Evaluation and Research.

[FR Doc. 94–5634 Filed 3–10–94; 8:45 am]

BILLING CODE 4160–01–P

[Docket No. 92E–0472]

Determination of Regulatory Review Period for Purposes of Patent Extension; Sporanox®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Sporanox® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product,

medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Sporanox®. Sporanox® (itraconazole) is indicated for the treatment of the following fungal infections in immunocompromised and nonimmunocompromised patients: (1) blastomycosis, pulmonary and extrapulmonary, and (2) histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Sporanox® (U.S. Patent No. 4,267,179) from Janssen Pharmaceutica N.V., and the Patent and Trademark Office requested FDA's assistance in determining this patents's eligibility for patent term restoration. FDA, in a letter dated December 8, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Sporanox® represented the first commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Sporanox® is 2,990 days. Of this time, 2,155 days occurred during the testing phase of the regulatory review period, while 835 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: July 7, 1984. The applicant claims June 7, 1984, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 7, 1984, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: May 31, 1990. The applicant claims May 30, 1990, as the date the new drug application (NDA) for Sporanox® (NDA 20–083) was initially submitted. However, FDA records indicate that NDA 20–083 was initially submitted on May 31, 1990.

3. *The date the application was approved*: September 11, 1992. FDA has verified the applicant's claim that NDA 20–083 was approved on September 11, 1992.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,510 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 10, 1994, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before September 7, 1994, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 28, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 94–5635 Filed 3–10–94; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the meeting of the Cardiovascular and Renal Drugs Advisory Committee, which is scheduled for March 24 and 25, 1994. This meeting was announced in the **Federal Register** of February 25, 1994 (59 FR 9219 at 9220). The amendment is being made to change both the starting times of the meetings for March 24 and 25, 1994, and revise the agenda for the open committee discussion of the meeting of March 25, 1994. Both amendments will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT: Joan C. Standaert, Center for Drug Evaluation and Research, Food and Drug Administration, 234 Summit St., Toledo OH 43604, 419–259–6211 or

Valerie M. Mealy, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–443–4695.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 25, 1994 (59 FR 9219 at 9220), FDA announced that a meeting of the Cardiovascular and Renal Drugs Advisory Committee would be held on March 24 and 25, 1994. On page 9220, column 1, the "Date, time, and place," "Type of meeting and contact person," and the "Open committee discussion" portions of this meeting are amended to read as follows:

Date, time, and place. March 24 and 25, 1994, 9 a.m., conference rms. D and E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, March 24, 1994, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; open committee discussion, March 25, 1994, 9 a.m. to 5 p.m.

Open committee discussion. On March 24, 1994, the committee will discuss new drug application (NDA) 20–390 (vesnarinone), Arkin®, Otsuka America Pharmaceutical, for congestive